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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,155	07/17/2003	Tongtong Wang	210121.455C20	2353

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,155	WANG ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4 and 11-13, drawn to an isolated polynucleotide comprising the sequence as cited in the claim, an expression vector comprising said polynucleotide, a host cell transformed with said expression vector, and a composition comprising said polynucleotide, and a method for stimulating immune response in a patient or for the treatment of a lung cancer in a patient by using said composition, classified in classes 536, 435 and 514, subclasses 23.5, 320.1 and 44, respectively.

II. Claims 2, 7 and 11-13, drawn to an isolated polypeptide comprising the amino acid sequence as recited, a fusion protein comprising the polypeptide as cited in claim 2, a composition comprising the polypeptide as cited in claim 2, and a method for stimulating immune response in a patient or for treating a lung cancer in a patient with said composition, classifiable in classes 514, 424 and 530, subclasses 2, 192.1 and 350, respectively.

III. Claims 5 and 11-13, drawn to an isolated antibody or an antigen-binding fragment thereof that specifically binds to a polypeptide recited in claim 2, a composition comprising said antibody, and a method for stimulating an immune response or treating a lung cancer in a patient with said composition, classifiable in classes 530 and 424, subclasses 387.1 and 130.1, respectively.

IV. Claims 6 and 16, drawn to a method for determining the presence of a cancer in a patient by using a binding agent, such as an antibody, that binds to a polypeptide of claim 2, and a diagnostic kit containing the antibody according to claim 5, classified in class 435, subclasses 7.1 and 810.

V. Claims 8, 14 and 15, drawn to a method for determining the presence of a lung cancer in a patient by using oligonucleotide that hybridizes to a sequence as recited in claim 8, said oligonucleotide, and a diagnostic kit containing said oligonucleotide, classifiable in classes 536 and 435, subclasses 24.3 and 6, 810, respectively.

VI Claim 9, drawn to a method for stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with polypeptides as cited, classifiable in classes 514 and 435, subclasses 2 and 372.3, respectively.

VII Claim 9, drawn to a method for stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with polynucleotides as cited, classifiable in classes 514 and 435, subclasses 44 and 372.3, respectively.

VIII. Claim 9, drawn to a method for stimulating and/or expanding T cells specific for a tumor protein by contacting T cells with an antigen presenting cell that expresses the polypeptide as cited, classifiable in classes 424 and 435, subclasses 93.7 and 372.2, 372.3, respectively.

IX. Claims 10-13 and 17, drawn to isolated T cells prepared by contacting T cells with polypeptide, a composition comprising said T cells, and a method for stimulating an immune response or treating a lung cancer in a patient with said composition, classifiable in classes 530 and 435, subclasses 350 and 372.3, respectively.

X. Claims 10-13 and 17, drawn to isolated T cells prepared by contacting T cells with polynucleotide, a composition comprising said T cells, and a method for stimulating an immune response or treating a lung cancer in a patient with said composition, classifiable in classes 424 and 435, subclasses 93.21 and 372.3, respectively.

XI. Claims 10-13 and 17, drawn to isolated T cells prepared by contacting T cells with antigen presenting cells that express a polypeptide, a composition comprising said T cells, and a method for stimulating an immune response or treating a lung cancer in a patient with said composition, classifiable in classes 424 and 435, subclasses 93.7 and 372.2, 372.3, respectively.

XII. Claims 11-13, drawn to a composition comprising an antigen-presenting cell expressing the polypeptide, and a method for stimulating an immune response or treating a cancer in a patient with said composition, classifiable in classes 435 and 424, subclasses 372.2 and 184.1.

Claim 9 links to inventions VI-VIII. Claims 10 and 17 link to inventions IX-XI. Claims 11-13 link to inventions I-III and IX-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 4 and 16-18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

II. The inventions are distinct, each from the other because of the following reasons:

Groups I-III and XII are distinct from each other because they are drawn to compositions having different chemical structures, physical properties and biological functions, and requiring separate search: polynucleotides, polypeptides, antigen-presenting cells and antibodies. Search for polynucleotides does not require search for antigen-presenting cells, polypeptides or antibodies, search for polypeptides does not require search for antibodies, antigen-presenting cells or polynucleotides, and so forth. Since the classification for each is different, the search for each group would not be coextensive. They are not obvious variants and deemed patentably distinct. Similarly, groups X and XI are patentably distinct from each other for the same reason.

Groups IV and V are distinct from each other because they are drawn to materially different methods using compositions having different chemical structures, physical properties and biological functions, and requiring separate search: antibodies vs. oligonucleotides. They are different methods that differ at least in method steps, reagents and/or dosages, schedules used, response variables, and criteria for success. They have different classifications and require separate search. They are not obvious variants and deemed patentably distinct.

Groups VI-VIII are distinct from each other because they are drawn to materially different methods using compositions having different chemical structures, physical properties and biological functions, and requiring separate search: polypeptides, polynucleotides, and antigen-presenting cells. They are different methods that differ at least in method steps, reagents and/or dosages, schedules used, response variables, and criteria for success. They have different classifications and require separate search. They are not obvious variants and deemed patentably

distinct. Similarly, groups IX-XI are distinct from each other for the same reasons as discussed above.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for detecting the presence of a protein in a sample or be used for purifying a protein via affinity chromatography. Thus, groups III and IV are distinct from each other.

Groups I-III and IX-XII are drawn to materially distinct methods using different compositions: polynucleotides, polypeptides, antibody, T cells prepared by contacting T cells with polypeptides, T cells prepared by contacting T cells with antigen presenting cells, T cells prepared by contacting polynucleotides, and antigen-presenting cells. The methods differ at least in method steps, reagents and/or dosages, schedules used, response variables, and criteria for success. Therefore, they are patentably distinct.

Groups I-III and IX-XII, group IV-V, and groups VI-VIII are distinct from each other because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. A method for stimulating an immune response or treating a cancer in a patient, a method for determining the presence of a lung cancer in a patient by using an antibody or oligonucleotide, and a method for stimulating and/or expanding T cells specific for a tumor protein are different methods with different objectives, different reagents and/or dosages, different method steps and

response variables. Thus, groups I-III and IX-XII, group IV-V, and groups VI-VIII are patentably distinct from each other. They have different classifications and require separate search.

Upon election of any group from groups I-XII, a **further restriction** (not election of species) is required as follows:

Since the SEQ ID Nos recited in the claims of the present application were isolated by a PCR-based subtraction of cDNA libraries prepared from human lung tumors and human normal cells, they represent different and distinct DNA sequences derived from different genes. The chemical structures of different genes are different from each other and their gene product functions also differ from each other. Thus, the SEQ ID Nos recited in the claims of the present application are patentably distinct from each other and require separate search. Applicant is required to elect a **single** SEQ ID No. for consideration by examiner.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

S Chen

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER